**Trial Description**

**Title**

BIOLAP: Biological versus synthetic mesh in laparoscopic hernia repair—a randomized multicenter, prospective, self-controlled clinical trial

**Trial Acronym**

BIOLAP

**URL of the trial**

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**Brief Summary in Lay Language**

Inguinal hernia repair is one of the most common surgical operations globally, more than 20 million groin hernias are repaired annually worldwide. The surgical techniques used to manage inguinal hernias are primary open repair, open repair with mesh, and laparoscopic repair with mesh. Laparoscopic repairs provide very good results including low postoperative pain, fewer wound infection, and quick return to daily activity and working. Recurrence after inguinal hernia operation is a considerable clinical problem. Another remaining problem after hernia surgery is the occurrence of chronic pain. Up to now, the use of synthetic meshes is the standard procedure, but there is raising evidence, that biological meshes could be of an advantage concerning occurrence of chronic pain due to a different postoperative remodeling without the disadvantages of a life-long implant. Since there is no trial that assessed the use of biological meshes in laparoscopic hernia repair, we want to show the advantages of this type of mesh. We will conduct a double-blinded trial, self-controlled design meaning every patient is his/her own control. This is possible in bilaterally occurring diseases, preventing from confounding factors such as surgeon's experience and patient factors such as metabolic diseases, ability of wound healing etc. Primary endpoints will be the incidence of postoperative local pain separately evaluated for each operational side per patient and the incidence of recurrent hernia within the first 2 years after operation.

**Brief Summary in Scientific Language**

The objective of the trial is to show a reduction of pain after laparoscopic inguinal hernia repair (TEP or TAPP) when using a biological mesh without increasing the recurrence rate in comparison to a synthetic mesh implant.

**Organizational Data**

- DRKS-ID: **DRKS00010178**
- Date of Registration in DRKS: **2016/06/16**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
DRKS-ID: **DRKS00010178**
Date of Registration in DRKS: **2016/06/16**
Date of Registration in Partner Registry or other Primary Registry: **[---]**

- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: 105/2017, Ethik-Kommission der Universität Witten/Herdecke

### Secondary IDs

### Health condition or Problem studied

- ICD10: **K40.20** - [generalization **K40.2**: Bilateral inguinal hernia, without obstruction or gangrene]

### Interventions/Observational Groups

- **Arm 1:** Biological mesh in laparoscopic hernia repair for one of the bilateral hernias.
  Endoscopic hernia repair (TAPP or TEP) has to be performed as described in the “Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal Hernia”, published bei the International Endohernia Society (IEHS). The same procedure has to be used for both sides.
- **Arm 2:** Synthetic mesh in laparoscopic hernia repair for the other hernia in the same patient, using the same implantation technique.
  Endoscopic hernia repair (TAPP or TEP) has to be performed as described in the “Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal Hernia”, published bei the International Endohernia Society (IEHS). The same procedure has to be used for both sides.

### Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: **[---]**
- Allocation: Randomized controlled trial
- Blinding: **[---]**
- Who is blinded: patient/subject
- Control: Active control (effective treatment of control group)
- Purpose: Treatment
Study Type: Interventional
Study Type Non-Interventional: [---]*
Allocation: Randomized controlled trial
Blinding: [---]*
Who is blinded: patient/subject
Control: Active control (effective treatment of control group)
Purpose: Treatment

- Assignment: Parallel
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): No

Primary Outcome

The unit of analysis is the hernia, not the patient. The study has two primary endpoints.
1. Incidence of postoperative local pain at the hernia site at six months after operation measured with a visual analogue scale (VAS 0-10)
2. Incidence of recurrent hernia within the first two years after operation

The total duration of follow-up per patient will be 2 years.

Intended trial visits: PRE = pre-operative assessment; OP = surgical procedure; F-1W, F-6M, F-12M, F-24M: clinical follow-up visit and assessment of endpoints at one week, six months, one year and two years after surgery. Scope of the follow-up visits: clinical examination, evaluation of pain (VAS on each side), complications, patient satisfaction, and recurrence. If a hernia recurrence was suspected, a verification with ultra-sound or MR or CT-scan will be performed.

Secondary Outcome

- prevalence and intensity of local pain at other time points (one week and one year postoperatively)
- early recurrences within the first year after surgery
- wound infection
- hematoma
- seroma
- patient satisfaction (overall results, foreign body sensation, paraesthesia)

Intended trial visits: PRE = pre-operative assessment; OP = surgical procedure; F-1W, F-6M, F-12M, F-24M: clinical follow-up visit and assessment of endpoints at one week, six months, one year and two years after surgery. Scope of the follow-up visits: clinical examination, evaluation of pain (VAS on each side), complications, patient satisfaction, and recurrence. If a hernia recurrence was suspected, a verification with ultra-sound or MR or CT-scan will be performed.

Countries of recruitment
Locations of Recruitment

- University Medical Center Hernienzentrum Köln-Merheim, Köln
- Medical Center Asklepios Westklinikum, Hamburg
- Medical Center PAN-Klinik, Köln
- Medical Center St. Elisabeth-Krankenhaus, Dorsten
- Medical Center Vinzenz Pallotti Hospital, Bergisch Gladbach
- Medical Center Wilhelmsburger Krankenhaus Groß-Sand, Hamburg
- Medical Center St. Marien-Krankenhaus, Ahaus
- Medical Center Helios Klinik, Attendorn
- Medical Center Johanniter-Hospital, Bonn
- Medical Center Josephs-Hospital, Warendorf
- Medical Center Klinikum Leverkusen, Leverkusen
- Medical Center DRK-Krankenhaus, Luckenwalde
- Medical Center St. Barbara-Klinik, Hamm-Heessen
- Medical Center GRN-Klinik, Weinheim
- Medical Center Ev. Diakonissenkrankenhaus, Leipzig
- Medical Center Eduardus-Krankenhaus, Köln
- Medical Center Lukaskrankenhaus, Neuss
- Medical Center Ev. Krankenhaus Köln-Weyertal, Köln
- Medical Center Ammerland-Klinik, Westerstede
- Medical Center St. Bernhard-Hospital, Kamp-Lintfort
- University Medical Center Uniklinik der RWTH, Aachen
- Medical Center Dreifaltigkeits-Krankenhaus, Wesseling

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/08/17**
- Target Sample Size: **496**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria
DRKS-ID: DRKS00010178
Date of Registration in DRKS: 2016/06/16
Date of Registration in Partner Registry or other Primary Registry: [---]*

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

1. Male or female patient at an age of 18 years or older
2. Primary, bilateral hernias
3. Patient eligible for laparoscopic hernia repair
4. Written informed consent

Exclusion criteria

1. Recurrent hernia
2. Incarcerated hernia
3. Presence of any acute systemic infection
4. Expected non-compliance with any study-related requirement

Addresses

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Contact for Public Queries

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Sources of Monetary or Material Support

- Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

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Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [--]*

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) Studienprotokoll BIOLAP-Studie